K093791

MAR 22 2010

510(K) SUMMARY

Device Name:	**GORE DrySeal Sheath**
Proprietary Name:	GORE DrySeal Sheath
Common Name:	Introducer Sheath
Classification Name:	Catheter, Introducer (per 870.1340)
Device Classification:	Class II
Product Code:	DYB
Date Summary Prepared:	December 9, 2009 (revised March 12, 2010)
Contact Person:	Alicia L. Hemphill Regulatory Affairs Medical Products Division W. L. Gore & Associates, Inc. 3450 West Kiltie Lane Flagstaff, AZ 86002-0500 Telephone: (928) 864-4328 Facsimile: (928) 864-4304 E-mail: *ahemphil@wlgore.com*

Intended Use

GORE DrySeal Sheath is intended to be inserted in the vasculature to provide a conduit for the insertion of endovascular devices while minimizing blood loss associated with such insertions.

Device Description

The GORE DrySeal Sheath consists of an introducer sheath with GORE DrySeal Valve attached, a dilator, and a syringe. The introducer sheath is a polyethylene tube with a tapered leading tip and marker band incorporated within the sheath material to allow identification under fluoroscopy. The sheath has an insert molded hub on the trailing end, which is attached to the GORE DrySeal Valve.

The GORE DrySeal Valve is comprised of an outer silicone tube and an inner film tube. The region between the silicone tube and film tube is pressurized by injecting 2.5mL of saline into the space, using the provided syringe, during procedural preparation of the device.

The dilator has a tapered leading end and provides dilatation of the access vessel. A mark on the trailing end of the dilator ensures correct positioning of the dilator within the sheath.

Predicate Devices

In terms of intended use, design, material composition and technological characteristics, the GORE DrySeal Sheath is substantially equivalent to the predicate devices. *In vitro* testing demonstrated that the GORE DrySeal Sheath met established acceptance criteria and that performance is comparable to the following predicate devices:

- **GORE Introducer Sheath**
  W. L. Gore & Associates, K013282

  The GORE Introducer Sheath is comprised of the introducer sheath and dilator. The introducer sheath is composed of a sheath, sheath hub and cap, and hemostasis valve. The dilator is composed of a dilator tube and dilator valve body. The GORE Introducer Sheath is designed to provide easy access to the vascular system while providing convenient temporary closure of the access site during catheter exchanges. The device allows introduction of angiographic catheters, balloon catheters, other relevant catheters, guidewires and endovascular devices into a vessel.

- **GORE Introducer Sheath with Silicone Pinch Valve**
  W. L. Gore & Associates, K032073, K082356

  The GORE Introducer Sheath with Silicone Pinch Valve is an introducer sheath comprised of a sheath with an attached valve system, hemostasis caps and a dilator. The tip of the dilator is tapered to facilitate atraumatic insertion of the sheath. The valve system helps maintain hemostasis during endovascular procedures.

Technological Characteristics and Substantial Equivalence

The GORE DrySeal Sheath is substantially equivalent to the GORE Introducer Sheath with Silicone Pinch Valve (K032073, K082356) and the GORE Introducer Sheath (K013282). Devices comparisons show all products have similar intended use, French size, sheath effective length, tip configuration, lumen, flushing system, materials, sterilization method and packaging materials. All products are supplied as single use, sterile products.

Bench / Performance Data

The following in-vitro testing was performed on the GORE DrySeal Sheath in accordance with ISO standards and/or internal procedures to assure reliable design and performance. In-vitro design verification testing data demonstrate that the device is in compliance with ISO 11070 Sterile, single use intravascular catheter introducers and product labeling.

- Sheath Working Length
- Dilator Length
- Guidewire Compatibility
- Sheath Tip to Dilator Transition
- Sheath/Valve Assembly Length
- Dimensional Compatibility with Devices
- Radiodetectability
- Tortuosity
- Kink Resistance
- Force at Break
- Strength of Union
- Removal Force
- Freedom from Leakage

Design Verification testing was conducted on the 12 Fr and 26 French Size sheaths. The testing demonstrated acceptable results.

Biocompatibility

In accordance with ISO 10993-1:2003, the following biocompatibility tests were conducted on the GORE Dry Seal Sheath:

- Cytotoxicity
- Sensitization
- Intracutaneous Toxicity
- Systemic Toxicity
- Hemocompatibility
- Hemolysis
- Prothrombin Time
- Complement Activation
- Thrombogencity
- Pyrogencity

Results for all biocompatibility testing demonstrate that the materials used meet the requirements of ISO 10993.

Conclusion

The studies conducted on the GORE DrySeal Sheath demonstrate that the device is substantially equivalent to the predicate devices currently in commercial distribution.

The proposed device meets the performance criteria of design verification as specified by ISO standards and test protocols. The proposed device has the same intended use, size, technology, design and materials as the predicate devices. Any differences between the devices do not raise any significant issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

W.L. GORE & Associates, Inc.
c/o Ms. Alicia L. Hemphill
Regulatory Affairs Associate
3450 West Kiltie Lane
Flagstaff, AZ 86003-2400

MAR 2 2 2010

Re: K093791
Trade/Device Name: GORE DrySeal Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II (two)
Product Code: DYB
Dated: March 12, 2010
Received: March 15, 2010

Dear Ms. Hemphill:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number (if known): ~~TBD~~ K093791

Device Name: GORE DrySeal Sheath

Intended Use / Indication For Use: The GORE DrySeal Sheath is intended to be inserted in the vasculature to provide a conduit for the insertion of endovascular devices while minimizing blood loss associated with such insertions.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vickers

(Division Sign-Off)
Division of Cardiovascular Devices

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